

## **REMARKS**

### **Amendments**

The original claims are amended to delete superfluous language and to use language in accordance with conventional US practice. These amendments do not narrow the scope of the claims. Also, claims 1, 14 and 15 are amended to describe the possible substituents for alkyl groups (see, e.g., the text bridging pages 15-16) and claims 1 and 15 are amended to recite a synergistic ratio (see, e.g., original claim 14). Further, claim 1 is amended to recite a composition, rather than a combination (see, e.g., page 9, lines 11-14). Compare claim 14 which recites a combination.

New claims 26-62 are directed to further aspects of applicants' invention and are supported throughout the specification. See, e.g., page 8, lines 14-27, page 9, lines 11-14, page 9, lines 29-31, page 10, lines 1-8, page 15, lines 5-16, page 16, line 10-page 17, line 9, 13, page 16, lines 18-23, and the Examples (e.g., treatment schemes e) and f ) at page 26).

### **Claim Objections**

Claims 1, 14, 15, and 24 are amended above to delete the phrase "selected from the group comprising," and claims 17-23 are amended so as to employ less allegedly "awkward" language. These amendments do not narrow the scope of the claims.

### **Rejection of Claim 24 under 35 USC §112, first paragraph**

While applicants do not agree with the assertion that claim 24 is not enabled, for purposes of furthering prosecution claim 24 is cancelled.

### **Rejection of Claims 16 and 23 under 35 USC §112, second paragraph**

Claim 16 depends from claim 15, and claim 15 recites the administration of a compound of formula (I) and a Bcr-Abl tyrosine kinase inhibitor. Since these two compounds are administered, it is inherent that each time they are administered they are administered at some "ratio." Thus, the "antecedent basis" for the ratio is implicit, but is also inherent. Thus, it is respectfully submitted that there is more than adequate antecedent basis

for the recitation of "the ratio" in claim 16. As for claim 23, this claim is cancelled as a result of the amendment to claim 15.

Withdrawal of the rejection under 35 USC §112, second paragraph, is respectfully requested.

**Rejection under 35 USC §102(a)**

The Nada et al. abstract lists 7 co-authors, including the two inventors. The results discussed in this abstract are not the work of "another" under 35 USC §102(a), but are instead the work of the inventors.

Applicants are filing herewith Declarations under Rule 132 by each of the two inventors. These Declarations confirm that, to the extent the claimed invention is disclosed in these publications, such disclosures are of the invention of Francis Giles and Srdan Verstovsek, the two co-inventors of the present application. Therefore, this abstract does not constitute prior art with respect to the claimed invention. See, e.g., *In re Katz*, 687 F.2d 450, 215 USPQ 14 (CCPA 1982).

For the reasons discussed above, withdrawal of the rejection under 35 USC §102(a) is respectfully requested.

**Rejection under 35 USC §103(a) in view of Jolivet et al. (US 6,645,972)**

Claims 1-23 and 25 are rejected as allegedly being obvious in view of Jolivet et al. (US 6,645,972). This rejection is respectfully traversed.

In the rejection, it is alleged that Jolivet et al. (US '972) discloses treating patients who are suffering from leukemia and who have been previously treated with a Bcr-Abl tyrosine kinase inhibitor such as imatinib mesylate, with a compound of applicants' Formula I, such as (-)-β-L-Dioxolane-Cytidine. However, it is acknowledged in the rejection that Jolivet et al. (US '972) fails to disclose administering to a patient a compound of applicants' Formula I in combination with a Bcr-Abl tyrosine kinase inhibitor such as imatinib mesylate. To address this discrepancy in the disclosure of US '972, the rejection asserts that it would be obvious to use not only a compound of applicants' Formula I, but also a Bcr-Abl tyrosine kinase inhibitor such as imatinib mesylates, to treat patients who are suffering from leukemia because both types of compounds are known for treating leukemia.

However, the rejection fails to explain why one would use a Bcr-Abl tyrosine kinase inhibitor, alone or in combination with any other active agent, to treat a patient suffering from leukemia, when that patient has already been treated with a Bcr-Abl tyrosine kinase inhibitor.

Moreover, US '972 provides no suggestion that a combination of a compound of applicants' Formula I and a Bcr-Abl tyrosine kinase inhibitor, such as imatinib mesylate, would exhibit synergistic results in the treatment of patients suffering from leukemia, as shown in applicants' disclosure, **and as noted in the Examiner's rejection under 35 USC §103(a) in view of the Nada et al. abstract.** The Examiner has described the Nada et al. abstract as demonstrating synergistic results for the claimed combination, and, as discussed above, Nada et al. is a disclosure of applicants' invention.

In view of the above remarks, it is evident that US '972 fails to render obvious applicants' claimed invention. Withdrawal of the rejection under 35 USC §103(a) is respectfully requested.

**Rejection under 35 USC §103(a) in view of Gourdeau et al. (WO 00/57861)**

Claims 1-23 and 25 are rejected as allegedly being obvious in view of Gourdeau et al. (WO 00/57861). This rejection is respectfully traversed.

In the rejection, it is alleged that Gourdeau et al. (WO '861) discloses treating patients who are suffering from leukemia with a compound of applicants' Formula I, such as (-)- $\beta$ -L-Dioxolane-Cytidine. However, it is acknowledged in the rejection that Gourdeau et al. (WO '861) fails to disclose administering to a patient a compound of applicants' Formula I in combination with a Bcr-Abl tyrosine kinase inhibitor such as imatinib mesylate. To address this discrepancy in the disclosure of WO '861, the rejection asserts that it would be obvious to use not only a compound of applicants' Formula I, but also a Bcr-Abl tyrosine kinase inhibitor such as imatinib mesylates, to treat patients who are suffering from leukemia because both types of compounds are known for treating leukemia, in light of the FDA article that is asserted to disclose that imatinib mesylates is approved for treatment of CML.

However, WO '861 provides no suggestion that a combination of a compound of applicants' Formula I and a Bcr-Abl tyrosine kinase inhibitor, such as imatinib mesylate, would exhibit synergistic results in the treatment of patients suffering from leukemia, as shown in applicants' disclosure, and as noted in the Examiner's rejection under 35 USC

§103(a) in view of the Nada et al. abstract. The Examiner has described the Nada et al. abstract as demonstrating synergistic results for the claimed combination, and, as discussed above, Nada et al. is a disclosure of applicants' invention.

In view of the above remarks, it is evident that WO '861 fails to render obvious applicants' claimed invention. Withdrawal of the rejection under 35 USC §103(a) is respectfully requested.

**Rejection under 35 USC §103(a) in view of Chu et al. and Zimmerman et al.**

While applicants do not agree with the assertion that claim 24 is rendered obvious by the combined disclosures of Chu et al. and Zimmerman et al., for purposes of furthering prosecution claim 24 is cancelled.

**Obviousness-Type Double Patenting Rejection in view of Jolivet et al. (US 6,645,972)**

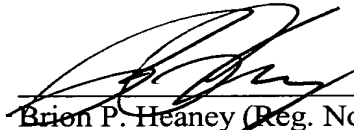
Claims 15-23 are rejected as allegedly being obvious in view of claims 1-24 of Jolivet et al. (US 6,645,972). This rejection is respectfully traversed.

As discussed above, the disclosure of US '972 does not suggest the synergistic results associated with applicants' claimed invention. Thus, the claims of US '972, obviously, also fail to suggest the synergistic results associated with applicants' claimed invention.

Hence, the claims of US '972 fail to render obvious applicants' claimed invention. Withdrawal of the obviousness-type double patenting rejection is respectfully requested.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

  
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Filed: October 19, 2005